DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-601/SLR-020

Schering Corporation
2000 Galloping Hill Road
Kenilworth, New Jersey 07033

Attention: Mary Jane Nehring
Senior Director, Regulatory Affairs

Dear Ms. Nehring:

Please refer to your supplemental new drug application dated January 7, 2002, and amendment dated May 31, 2002, received January 8, 2002, and June 3, 2002, submitted under section 505(b)/pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for OPTIMINE (azatadine maleate USP) Tablets.

This supplemental new drug application provide for revisions to the OVERDOSAGE section of the Package Insert.

We have completed our review of this application as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revisions listed below which was agreed to in a telephone conversation on August 22, 2002, between Valerie Cotler, Regulatory Affairs Manager at Schering, and Colette Jackson, Project Manager.

Revise the statement OPTIMINE Tablets, USP, 1 mg in the HOW SUPPLIED Section to state azatadine maleate USP.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the enclosed labeling (text for the package insert, text for the patient package insert, immediate container and carton labels) and/or submitted labeling (product information sheet submitted January 7, 2002). These revisions are terms of the approval of this application.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 17-601/S-020." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Colette Jackson, Project Manager, at (301) 827-5584.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, MD, Ph.D.
Acting Director
Division of Pulmonary and Allergy Drug Products, HFD-570
Office of Drug Evaluation II
Center For Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Badrul Chowdhury
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